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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/765,466	01/26/2004	Sachiko Machida	690115.401C1	8356

500 7590 09/11/2009

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EXAMINER	
YU, MELANIE J	

ART UNIT	PAPER NUMBER
1641	

MAIL DATE	DELIVERY MODE
09/11/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/765,466	MACHIDA ET AL.	
	Examiner	Art Unit	
	MELANIE YU	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 June 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,17,44 and 45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,17,44 and 45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/4*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment filed 19 June 2009 has been entered.

Status of the Claims

2. Claims 2-16 and 18-43 have been canceled. Claims 1, 17, 44 and 45 are currently pending and are examined on the merits.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on 4 February 2009 has been considered by the examiner.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Holtzman (US 5,969,123) in view of Schatz (US 5,932,433) further in view of Kakutani et al. (Accumulation of LOX-1 Ligand in Plasma and Atherosclerotic Lesions of Watanabe

Heritable Hyperlipidemic Rabbits: Identification by a Novel Enzyme Immunoassay, Biochemical and Biophysical Research Communications, 2001, Vol. 282, pages 180-185).

Holtzman teaches a biochip for a screening assay (col. 12, lines 7-8) comprising a biotinylated receptor protein immobilized via a factor capable of specifically binding to biotin (streptavidin specifically binds to biotin and the biotinylated proteins is immobilized to the streptavidin, col. 12, lines 8-16), wherein the receptor protein comprises a biotinylation sequence motif (biotinylated protein comprises biotinylation sequence motif, col. 12, lines 11-16), and wherein the receptor protein has the ability of being specifically bound by a ligand of the receptor protein (col. 8, line 65-col. 9, line 6). Holtzman differs from the instant claims by failing to teach a recombinantly expressed biotinylated receptor protein and the receptor specifically being an extracellular region or a C-type lectin-like domain of a scavenger receptor LOX-1.

Schatz teaches a recombinantly expressed biotinylated receptor protein immobilized via a factor capable of specifically binding to biotin (peptides are biotinylated and bound to streptavidin which specifically binds to biotin, col. 8, lines 10-27, biotinylated peptide may be a protein, col. 6, lines 13-19), wherein the receptor protein comprises a biotinylation sequence motif (when peptides are biotinylated, they gain a biotinylation sequence motif, col. 8, lines 10-27; col. 4, lines 57-60), wherein the biotinylation of the receptor protein has been carried out within a bacterial host instead of in vitro (carried out in *E. coli* host cells, col. 3, lines 47-50; col. 8, lines 10-14), in order to provide a protein that has been biotinylated.

Kakutani et al. teach a recombinantly expressed receptor protein (recombinant soluble LOX-1, abstract, pg. 180; recombinant protein, right column, second paragraph, pg. 183), wherein the receptor protein has the ability of being specifically bound by an endogenous ligand of the receptor protein (extracellular domain of LOX-1 is prepared as part of the protein and binds to OxLDL, which is the endogenous protein of the ligand, section: *Specificity for the Recognition by LOX-Fc Fusion protein*, pg. 181) and wherein the receptor is an extracellular region of a scavenger receptor LOX-1 (extracellular domain of LOX-1 is fused to IgG and binds to OxLDL, therefore the receptor is the extracellular region of a scavenger receptor LOX-1, right column, second paragraph, pg. 183), in order to detect increased levels of OxLDL antigen which is positively correlated with atherosclerosis.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the biotinylation of the receptor protein of Holtzman, biotinylation in vivo instead of in vitro as taught by Schatz, in order to provide a simplified biotinylation process (Schatz, col. 2, lines 59-63). It would have further been obvious to one having ordinary skill in the art at the time the invention was made to include as the receptor protein of Holtzman in view of Schatz, a recombinantly expressed receptor protein that is an extracellular region of a scavenger receptor LOX-1 as taught by Kakutani et al., because Holtzman is generic with respect to the immobilized receptors that can be incorporated into the chip and one having ordinary skill in the art would be motivated to use the appropriate receptor ligand for detection of a desired analyte and to indicate increased or decreased susceptibility to

atherosclerosis. Although Holtzman in view of Schatz further in view of Kakutani et al. fail to specifically teach the immobilized receptor protein obtained by refolding a biotinylated receptor protein expressed as an inclusion body within the host, such a limitation is drawn to a method of making the protein on the chip. The instant claims encompass a product of the receptor chip and not a method of making the product, the LOX-1 immobilized on the chip as taught by the prior art must be the same receptor protein required by the claims. Since the combination of prior art references described above, teaches a recombinantly expressed LOX-1 receptor protein biotinylated in a bacterial host and then immobilized on the substrate via the biotinylation sequence motif, the combination of the prior art references teaches the required structural limitations of the claim and the recombinantly expressed extracellular region of a scavenger LOX-1 protein of the prior art reads on the claimed receptor being an extracellular region of a scavenger receptor LOX-1.

2. Claims 17 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brigham-Burke et al. (US 5,395,587) in view of Holtzman (US 5,969,123) further in view of Schatz (US 5,932,433) and Kakutani et al. (Accumulation of LOX-1 Ligand in Plasma and Atherosclerotic Lesions of Watanabe Heritable Hyperlipidemic Rabbits: Identification by a Novel Enzyme Immunoassay, Biochemical and Biophysical Research Communications, 2001, Vol. 282, pages 180-185).

Brigham-Burke et al. teach a protein immobilized on a SPR substrate (sensor chip, col. 5, lines 29-35; col. 5, lines 10-23) that conforms to a shape of an insertion site of a surface plasmon resonance device (sensor chip fits through a slot in the housing for

SPR detection, 14, Fig. 1; col. 5, lines 30-35), but fail to teach the protein being biotinylated and immobilized via a factor capable of binding specifically to biotin.

Holtzman in view of Schatz further in view of Kakutani et al., as applied to claim 1, teach a biotinylated receptor protein immobilized on a substrate via a factor capable of specifically binding to biotin, in order to provide immobilization of receptor proteins on a substrate.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include on the substrate of Brigham-Burke et al., an immobilization technique of a biotinylated receptor protein as taught by Holtzman in view of Schatz further in view of Kakutani et al., in order to simple and efficient immobilization of proteins on a substrate.

3. Claims 17 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muramatsu (Piezoelectric Crystal Biosensor Modified with Protein A for Determination of Immunoglobulins, 1987, Analytical Chemistry, vol. 59, pages 2760-2763) in view of Holtzman (US 5,969,123) further in view of Schatz (US 5,932,433) and Kakutani et al. (Accumulation of LOX-1 Ligand in Plasma and Atherosclerotic Lesions of Watanabe Heritable Hyperlipidemic Rabbits: Identification by a Novel Enzyme Immunoassay, Biochemical and Biophysical Research Communications, 2001, Vol. 282, pages 180-185).

Muramatsu teaches a protein immobilized on a crystal oscillator (pg. 2760, right column, last paragraph), but fail to teach the protein being biotinylated and immobilized via a factor capable of binding specifically to biotin.

Holtzman in view of Schatz further in view of Kakutani et al., as applied to claim 1, teach a biotinylated receptor protein immobilized on a substrate via a factor capable of specifically binding to biotin, in order to provide immobilization of receptor proteins on a substrate.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include on the substrate of Muramatsu, biotinylation of a protein receptor and immobilization via a factor capable of binding specifically to biotin as taught by Holtzman in view of Schatz further in view of Kakutani et al., in order to simple and efficient immobilization of proteins on a substrate.

Response to Arguments

4. The previous rejection under 35 USC 112, first paragraph has been withdrawn in light of applicant's amendment to claim 1.

5. Applicant's arguments with respect to claims 1, 17, 44 and 45 have been considered but are moot in view of the new ground(s) of rejection. Applicant's arguments with respect to the rejection under 35 USC 103(a) of claims 1, 17, 44 and 45, specifically the reference of Tall et al., have been fully considered and are persuasive. The previous rejections of the claims have been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of applicant's amendment requiring the new limitation of the receptor being an extracellular region or a C-type lectin-like domain and the prior art reference of Kakutani et al. teaching this limitation.

6. Applicant's argument that there is no evidence that the receptor protein has ever been produced from bacteria is not persuasive because the production of the receptor

protein from a bacterial host is drawn to a method of making the receptor protein. The prior art only needs to teach a receptor protein that is recombinantly expressed and the product by process limitation of the claim does not require the prior art to teach the exact method of making, as described in the rejection above.

Conclusion

7. No claims are allowed.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE YU whose telephone number is (571)272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie Yu/
Patent Examiner, Art Unit 1641